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| APPLICATION NO                                      | ). I                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-----------------------|-------------|----------------------|-------------------------|------------------|
| 10/079,416  | 10/079,416 02/22/2002 |             | Oliver Yoa-Pu Hu     | 39297-174170            | 8467             |
| 38598   | 7590                  | 11/13/2006  |                      | EXAMINER                |                  |
|   | VS KURT               |             | KIM, VICKIE Y        |                         |                  |
| 1350 I STREET, N.W. SUITE 1100 WASHINGTON, DC 20005 |                       |             |                      | ART UNIT                | PAPER NUMBER     |
|   |                       |             |                      | 1618                    |                  |
|   |                       |             |                      | DATE MAILED: 11/13/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| •   | Application No.  | Applicant(s)  |  |  |  |
|---|--|---|--|--|--|
|   | 10/079,416   | YOA-PU HU ET AL.  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit  |  |  |  |
| · ·   | Vickie Kim   | 1618  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply   |  |   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply if NO period for reply is specified above, the maximum statutory period w.  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).         | 36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | ely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133). |  |  |  |
| Status  |  |   |  |  |  |
| 1) Responsive to communication(s) filed on  2a) This action is <b>FINAL</b> . 2b) This  3) Since this application is in condition for allowar closed in accordance with the practice under E  | action is non-final.  nce except for formal matters, pro   |   |  |  |  |
| Disposition of Claims   |  |   |  |  |  |
| 4) ☐ Claim(s) 49 and 51 is/are pending in the applic 4a) Of the above claim(s) is/are withdrawn 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 49 and 51 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or  | n from consideration.  |   |  |  |  |
| Application Papers  |  |   |  |  |  |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examiner  | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj  | e 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).   |  |  |  |
| Priority under 35 U.S.C. § 119  |  |   |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |  |   |  |  |  |
| Attachment(s)   |  |   |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:   |   |  |  |  |

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#### **DETAILED ACTION**

## Status of Application

- 1. Acknowledgement is made of amendment filed 8/17/06. Upon entering the amendment, the claims 49 and 51 are amended and the claims 1-48 and 50 are canceled.
- 2. The claims 49 and 51 are pending and presented for the examination.

## Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 49 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively as being obvious over Burger et al(US5759556).

The claims are drawn to a topical composition comprising a mixture of terpineol and retinoic acid and a carrier for topical application.

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Burger et al teaches a composition comprising terpineol in combination with retinols or retinyl esters with cosmetically acceptable vehicle(see col.5) for treating a variety of unwanted skin conditions such as reduction of wrinkle or aged skin care and so on, see abstract and claim 1. Although Burger preferably uses retinol or retinyl esters because they are safer than retinoic acid, one would have been obvious to modify Burger's teaching to substitute retinol or retinyl esters with retinoic acid because Burger repeatedly mentioned that retinoic acid is more potent than retinol or retinyl esters for skin care activity, see col. 1, lines 54-56 and example 1. Retinoic acid has been known to pharmaceutical and cosmetic industries for many years where the side effects and safety concerns are well documented and have been managed by augmenting with coadministration of sun-screen or sun-block lotions. Thus, one skilled artisan readily envisaged a substitution of retinol or retinyl esters with retinoic acid, or alternatively, at least it would have been obvious to one of ordinary skill in the art to make such modification because the modification would improve industrial applicability by cost reduction and better patient satisfaction. Retinoic acid has high commercial value since retinoic acid has been formulated and sold successfully in market place for many years(Retin-A® or Renova®) as effective skin care products and thus, manufacturing or promoting such drug with retinoic acid would decrease manufacturing cost which eventually benefiting the customer. The efficacy was assured by Burger's teaching (use of retinol or retinyl esters to mimic the effect of retinoic acid, see abstract) and the safety has also well known in the state of art by numerous commercial products available in market place.

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Thus, the claimed invention is not patentably distinct over the prior art of the record.

Burger teaches the amount of terpineol(as a cyclic aliphatic unsaturated compound) present in about 0.0001%-50%, preferably 0.01%-10%, see claim 1.

As described in patent, all the critical elements required by the instant claims are well taught and the claims are properly included in anticipatory 102 rejection(envisaged), or at least obvious over the prior art of the record for the reasons set forth above.

6. Claims 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bortlik et al(US2002/0107292 A1) in view of Eini et al (US 5227163) and Burger et al(US5759556).

US'292(Bortlik et al) teaches a composition for inducing cytochromoe P450 monooxygenase, comprising a combination of terpenoids(from plant or natural source) and retinoid, see abstract and claim 7. Terpineol is a species of terpinoid and one would have been obvious to substitute terpinoid with terpineols when Botlik is taken ive view of Eini et al because Eini et al teaches that essential oils(from plants) has high content of terpineols(see col. 3,m lines 29-52) and thus easy access of terpineol is great advantages to end users because reduction of cost due to each access of raw materials and also retinoic acid is most potent retinoid as taught by Burger(see above, 102/103 rejection) and thus one would have motivated to substitute retinoids with retinoic acid to increase the quality. As mentioned earlier, retinoic acid and terpineol's efficacy and safety are well proven as evidenced by the reference cited herein, the modification

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would have been successfully done and thus, one would have been motivated to make a composition comprising a mixture of terpineol and retinoic acid with a dermatolocally acceptable carrier, with reasonable expectation of success because it is always desired to extend the selection options for better availability for manufacture or improvement of industrial applicability.

All the claimed invention is obvious and unpatentable since it is not patentably distinct over the prior art of the record.

### Conclusion

- 7. No claim is allowed. Having carefully reviewed applicants' Request for Reconsideration, the examiner maintained the rejection in any respect.
- 1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- 8. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM PRIMARY EXAMINER

Vickie Kim Primary Patent Examiner November 1, 2006 Art unit 1618